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cc: MTC@mchsi.com, Karen Florini <KFlorini@environmentaldefense.org>, Richard Denison <rdenison@environmentaldefense.org>
bcc:
Subject: Environmental Defense comments on Dechlorane Plus (CAS# 13569-89-9)

(Submitted via Internet 2/28/05 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, / boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and steve_b._kemp@oxy.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for **Dechlorane Plus (CAS# 13569-89-9)**.

The Occidental Chemical Company, in response to the HPV Challenge, has submitted robust summaries and a test plan for Dechlorane Plus. Our review indicates that this submission is well-organized and carefully written to describe available data to address the SIDS elements required by the HPV Challenge. A summary of available data and proposed further testing addressing a number of SIDS elements not currently adequately addressed is also provided in a Data Assessment Matrix and in a test plan summary.

However, we do not consider this submission complete. In spite of the fact that it is carefully organized and written, we would point out that most of the studies described in the robust summaries are old, poorly designed, and/or were not conducted under GLP, and many are not sufficient to address the requirements of the HPV Challenge.

Also we note that, while not required, important background information on production, transport and use(s) of this chemical has not been included in this submission -- information that is critical to an assessment of its risks

The chlorinated portions of Dechlorane Plus are identical to that of a number of now-prohibited insecticides, e.g., aldrin, dieldrin, endrin and others. These insecticides were banned because of their toxicity to wildlife, potential carcinogenicity and/or their persistence in the environment. It is reasonable to expect that a similar molecule such as Dechlorane Plus will share some of these unwanted properties. Dechlorane Plus is expected to be as persistent in the environment as these banned insecticides. This speculation on our part is supported by studies of biodegradation described in this submission.

The limited and poorly designed studies described in this submission indicate that Dechlorane Plus bioaccumulates in fish and most probably in mammals. The studies used to address the fate and toxicity of Dechlorane Plus are outdated and used study designs that may not have provided accurate assessments of its chronic toxicity. Very sparingly soluble chemicals such as Dechlorane Plus require study designs that take its insolubility into consideration. That has not been done. The fish toxicity studies of Dechlorane Plus used doses that exceeded its solubility by several-fold. Further, most studies of toxicity to mammals used doses that far exceeded the capacity of the animals to absorb it into the systemic circulation. Extrapolations of data from such studies give a false impression of its safety because they do not take into account the actual dose to the animal. Thus, whereas the cited data indicate Dechlorane Plus may have very little toxicity, that may not be the case. We believe that studies that used longer exposures to lower doses and thus provided opportunity for bioaccumulation, such as would occur in an environmental exposure, would have indicated greater toxicity of Dechlorane Plus. This speculation is based on results seen in studies of similar structurally related highly chlorinated and sparingly soluble compounds such as mirex and kepone, as well as in the results of the repeat dose studies described in the robust summaries of this submission. In the case of mirex, the total dose administered in repeat dose studies that killed all the animals was less than that reported as an acute LD_{50}.

Some evidence of metabolism and clearance of Dechlorane Plus is provided in the robust summaries. However, those studies were not well-designed and no metabolites were identified. It is also not obvious if the lipid-rich tissues, e.g. adipose tissue and skin, in which such lipophylic chemicals usually concentrate, were assayed. Studies using modern protocols and low doses should be conducted.

All data described in this submission are taken from internal company documents and, as such, are not available to the public. However, that said, we should note that this is another example of how the HPV Challenge in making at least summaries and results of such studies more available to the public.

Whereas we appreciate the fact that this very sparingly soluble chemical will be poorly absorbed when administered at acute high doses, we are concerned that long-term low-dose exposure may result in significant threats to environmental and human health. We support the additional studies proposed by the sponsor. However, we would stress that the studies of reproductive and developmental toxicity should be designed to address the adverse effects of chronic low-dose exposure on both parental health and that of the offspring. If possible, these studies should also include the use of radiolabeled material in order to facilitate the determination of the bioaccumulation of Dechlorane Plus in the dosed animals as well as its transfer to the offspring via both the placenta and milk.

In summary, we recommend that EPA defer acceptance of this submission until appropriate studies of Dechlorane Plus are proposed.

Thank you for this opportunity to comment.

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